report reiterated recommendations in an article published last week in the Journal of the American Medical Association. In particular, they stated:

The Institute of Medicine identified the imbalance in authority between the Office of New Drugs and the Office of Surveillance and Epidemiology as a major weakness in the drug safety system. In an effort to facilitate a collaborative and constructive team approach, the Institute of Medicine recommended joint authority for the Office of New Drugs and Office of Surveillance and Epidemiology in the postapproval setting.

These experts noted that the FDA's response to the Institute of Medicine's recommendations ''represent incremental progress'' but suggest that the FDA failed to embrace, among other things, ''the equality between the preapproval and postapproval activity of the agency.''

Having equality between the preapproval and postapproval activities at the FDA is fundamental to real reform. It is common sense. This is especially true when we think about what we have learned from the operation of the FDA over the past few years and those shortcomings.

As we debate this bill, we are going to hear a lot about the impressive Institute of Medicine study and its recommendations to improve the FDA. We have and will continue to hear Members talk about how S. 1082 addresses many of the Institute of Medicine's recommendations. However, this is one important and sweeping recommendation that is not addressed in the bill before us.

Amendment No. 1039 is intended to address that shortcoming. I have seen time and again in my investigations that serious adverse effects that emerge after a drug is on the market do not necessarily get the prompt attention they deserve. They are certainly not getting the attention from the Office of New Drugs.

Even the Government Accountability Office report entitled, ''Improvement Needed in FDA's Postmarket Decisionmaking and Oversight Process,'' stated:

FDA lacks clear and effective processes for making decisions about, and providing management oversight of, postmarket safety issues.

I, for one, have seen too many people suffer from the results of the Vioxx mess. I also have heard from parents whose children committed suicide on antidepressants.

This amendment is about making postmarketing safety in S. 1082 a reality, not just another byline. Identifying a safety issue after a drug is on the market is the beginning of the process of protecting the American consumer.

Once the safety questions are identified, FDA needs to be empowered and willing to take action to address those questions and to ensure timely notice to doctors and consumers of new safety risks for drugs that they are already taking.

Senator ENZI stated last Monday that with Vioxx, the Food and Drug Administration did not have enough tools to deal with the new risks that became evident only after Vioxx had been on the market for some time.

But the problem with the Vioxx mess and the antidepressant mess wasn't only about having enough tools, it was about FDA managers disregarding the concerns raised by its own scientists in the Office of Surveillance and Epidemiology and not taking action in a timely manner.

Amendment No. 1039, which is in the Institute of Medicine recommendations, is intended to curb delays when it comes to safety.

I have also been told by scientists and epidemiologists working in the FDA, as well as independent thought leaders, that S. 1082 as it stands will not prevent another Vioxx debacle.

They have told me that the Office of Surveillance and Epidemiology needs, at the minimum, joint postmarketing decisionmaking authority with the Office of New Drugs to ensure prompt postmarketing action.

I also am afraid to say, that right now, I am at the beginning of another review that will likely lead to concerns similar to those we have seen in the past—a situation where the postmarketing adverse events are severe and the public knows nothing.

The other amendment I want to talk about, amendment No. 998, is just plain common sense.

For FDA's new authorities to be meaningful, there has to be strong civil monetary penalties.

I hear that there is a lot of opposition to having stronger civil monetary penalties than those currently in S. 1082. But that just does not make sense to me.

Over the last week I have heard members talk about giving FDA some bite. Well, let's add some teeth.

Civil monetary penalties need to be more than the cost of doing business.

If civil monetary penalties are nothing more that the cost of doing business, you can't change behavior and, more importantly, you can't deter intentional bad behavior.

Amendment No. 998 would increase the penalties that can be imposed if companies fail to comply with the requirements of the ''risk evaluation and management strategies,'' such as labeling changes and requirements for postapproval studies or risk communication plans.

These requirements are at the core of S. 1082. But, FDA cannot be an effective regulator if it's all bark and no bite.

The last thing we need to do with this bill is to provide the FDA with new authorities but little enforcement capacity. That's not accountability and that won't help FDA do its job better for the American people, and it won't punish bad players.

That is why amendment Nos. 1039 and 998 make sense.

They fit into S. 1082 and its stated goal of promoting postmarketing safety.

I again thank Senators KENNEDY and ENZI for the tremendous efforts that went into bringing this bill to the floor, and I again thank them for incorporating a number of the provisions set forth in the two bills filed by Senator DODD and me.

Mr. President, I yield the floor.

ORDER OF PROCEDURE

Mr. KENNEDY. Mr. President, I understand there is a time allocation; am I correct?

The PRESIDING OFFICER. That is correct.

Mr. KENNEDY. Could the President tell us the time allocation remaining?

The PRESIDING OFFICER. The Republicans have 9 minutes remaining and the majority has 35 minutes.

Mr. KENNEDY. I note that the Senator from Maine was on the floor before I came down, and I know there are other Senators, Senator ROBERTS being one, who wanted to speak, and I think Senator BURR. We also have a number on our side.

My ranking member is here, and I imagine he will allocate the time on his side. I am glad to have the good Senator from Maine go ahead. I understand there are 9 minutes in total on her side.

Mr. President, I ask unanimous consent that I be allowed to follow her.

The PRESIDING OFFICER. Without objection, it is so ordered.

IMPORTATION OF PRESCRIPTION DRUGS

Ms. SNOWE. Mr. President, I thank the Senator from Massachusetts for his courtesy and for his cosponsorship of this initiative. I, obviously, want to also thank the sponsor of this legislation, with whom I am privileged to join, the Senator from North Dakota, who has demonstrated leadership for the last decade on this initiative which is so crucial to the American consumer.

I rise to speak today on behalf of the Dorgan-Snowe amendment regarding drug importation. I know the Senator from Mississippi, Mr. COCHRAN, has offered a second-degree amendment to require the Secretary of Health and Human Services certify both the savings and safety of drug importation. Obviously, there is concern for the safety of the American people. It is one that I appreciate strongly. It must be our highest priority. But we have been at this juncture before with respect to drug importation.

As I mentioned earlier, twice before we have seen the Congress adopt a requirement for the Secretary to certify safety and savings before implementing a program of prescription drug importation, and not a single prescription drug was imported under either the MEDS Act of 2000 or the Medicare Modernization Act of 2003. Americans deserve access to affordable medications, and that access must be safe, but